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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,095	03/16/2000	WOLF-GEORG FORSSMANN	P65141US0	5210

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/04/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/508,095

Applicant(s)

ZUCHT ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 14.

Claim(s) rejected: 13-17.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: see attached interview summary and PTO-892

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first and second paragraphs. In the amendment of June 27, 2003, claims 13-17 have been cancelled, new claims 18-29 have been added. Applicants' response has been fully considered, however, claims 18, 20-29 are rejected under 35 USC 112, first paragraph, claims 18, 24 and 29 are rejected under 35 USC 112, second paragraph, and claims 18 and 19 are objected to.

If applicants' amendment were entered, it would have the following response:

1. Claims 18, 20-29 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a peptide with a defined sequence such as SEQ ID NO:17 and SEQ ID NO:19 obtained from cow or human milk via a process of proteolytic cleavage and purification, and having bifidogenic properties; and a method of obtaining these peptides, does not reasonably provide enablement for a peptide obtained from cow or human milk via a process of proteolytic cleavage and purification, or, the N-terminal modified peptide having bifidogenic property, wherein the amino acid sequence of the peptide is not defined; a pharmaceutical composition containing the peptide; a method of obtaining these peptide; or a method of promoting the growth of bifidobacteria or inhibiting the growth of non-bifidobacteria, comprising administering the peptide to an individual. The specification only indicates the isolation and purification of certain peptides having bifidogenic properties (Example 1), the method of monitoring the growth-regulating activity on *E. coli* (Example 2), the method of monitoring the growth-regulating activity on *Bifidobacterium bifidum* (Example 3), and a formula to define bifidogenic activity (Example 4). However, the specification has not identified any N-terminal modified peptides having the bifidogenic property, and there are no working examples indicating the bifidogenic activities of these peptides. Furthermore, there is no in vitro or in vivo data indicating the peptide or the N-terminal modified peptide is effective in promoting the growth of bifidobacteria or inhibiting the growth of non-bifidobacteria in individual. Therefore, it is necessary to have additional guidance on the identity of the modified peptide, the use of the peptide for promoting the growth of bifidobacteria in individual, and to carry out further experimentation to assess the effect of the peptides with bifidogenic property in vivo. In response, applicants indicate the provided references have shown how to make N-modified peptide, e.g., by amidation, phosphorylation; and the determination of which N-modified peptide having bifidogenic activity does not involve undue experimentation (pages 9-11 of the response); Regarding the treatment of disease in accordance with the invention, applicants indicate the treating condition such as dose has been described in the specification, and it is not necessary to describe all embodiments in the specification, and the fragments have been removed (pages 12-13 of the response); and the first paragraph of 112 contains no requirement for a structural disclosure, a description in functional terms can satisfy the enablement requirement (page 14 of the response). The response has been fully considered, however, the argument is found persuasive because the specification has not shown the N-modified peptides possess the bifidogenic property as the certain parent peptides, and the provided reference does not provide all the teachings required for the claimed invention, e.g., the reference does not teach how to make N-terminal phosphorylated peptide, the references only indicate a peptide with Tyr or Ser can be phosphorylated at the side chain; regarding the treatment, there is no in vitro or in vivo data indicating the effect of the peptide; and the function of the peptide is closely related to its structure, without identification of the peptide, one skilled in the art would not know how to identify a functional peptide. Therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of these peptides.

2. Claims 18, 24 and 29 are rejected under 35 USC 112, second paragraph because of the use of the term "R1, R3 independently represents NH<sub>2</sub>" or "R2, R4 independently represents COOH, CONH<sub>2</sub>". It is not clear what group the N-terminal or C-terminal end of the peptide has since each amino acid (HN-CH(R)-CO) in the peptide has already contained the amino (NH) and carbonyl (CO) groups, e.g., if N-terminal of peptide is R1-A, and R1 =NH<sub>2</sub>, R1-A would be H<sub>2</sub>N-NH-CH(CH<sub>3</sub>)CO-, which is not a correct structure. In response, applicants indicate "NH<sub>2</sub>" and "COOH" at the amino and carboxyl ends is well known and used in the amino acid sequence (e.g., NH<sub>2</sub>-G-D-F-R-G-COOH) and is illustrated in Stryer, Biochemistry. The argument is not persuasive because the formula of amino acid in the peptide already includes both NH and CO group as indicated above, please see attached Voet & Voet "Biochemistry", pages 112-113.

3. Claims 18 and 19 are objected to because the claim contains recitation of non-elected sequences. Applicant has elected SEQ ID NO:22 for examination in Paper NO.11.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, first and second paragraphs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
July 31, 2003

*Christopher S. F. Low*

CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## Interview Summary

**Application No.**

09/508,095

**Applicant(s)**

ZUCHT ET AL.

**Examiner**

Chih-Min Kam

**Art Unit**

1653

All participants (applicant, applicant's representative, PTO personnel):

(1) Chih-Min Kam.

(3)\_\_\_\_\_.

(2) William Player.

(4)\_\_\_\_\_.

Date of Interview: 30 July 2003.

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: \_\_\_\_\_.

Identification of prior art discussed: \_\_\_\_\_.

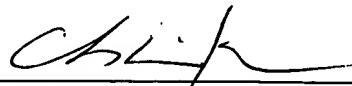
Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: to Inform the attorney the amendment after final has been received and will examine shortly.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.